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ART UNIT PAPER NUMBER

3308

DATE MAILED: 09/01/94

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 2 Nov 1993 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 1, 2, 5, 9-11, 16-17, 20, 24 and 26-40 are pending in the application.  
Of the above, claims — are withdrawn from consideration.
2. ☒ Claims 3, 4, 6-8, 12-15, 18, 19, 21-23 and 25 have been cancelled.
3. ☒ Claims 1, 2, 9-11, 16-17 and 20 are allowed.
4. ☒ Claims 24, 26-35, 37, 39 and 40 are rejected.
5. ☒ Claims 36 and 38 are objected to.
6. ☐ Claims — are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on —. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on —, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed —, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. —; filed on —.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Claims 29 and 40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 29, lines 5-6, and claim 40, line 8, there is no antecedent basis for "said introducer sheath".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 29 is rejected under 35 U.S.C. § 102(b) as being anticipated by Choudhury.

See figure 4, elements 28 and 44. (Note: Examiner is not giving any weight to the preamble of the claim as it is directed to the intended use of the device.)

Claims 24, 26, 27, 28, 31, 32, 33, 34, 35, 39 and 40 are rejected under 35 U.S.C. § 102(a) as being anticipated by Inoue (WO 91/12047).

With respect to claims 24, 28, 31, 39 and 40, Inoue discloses a tubular introducer sheath (figure 14B, element 8), a prosthesis (figure 14B, element 7), a self-expanding spring

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assembly (see figure 2), tubular carrier means (see figure 3, element 2); and means for retaining said prosthesis assembly at the particular position (see figure 11, element 23 and element 2). With respect to providing access to the lumen, see column 3, lines 17-24.

With respect to claim 26 and 33, see column 8, lines 48-56 and figure 11, element 23.

With respect to claim 27, see figure 3, element 3.

With respect to claim 32, see figure 11; for attachment means, see element 21.

With respect to claims 34 and 35, see figure 11, element 4 and element 3.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same

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person.

Claim 37 is rejected under 35 U.S.C. § 103 as being unpatentable over Inoue in view of Choudhury.

With respect this claim, Inoue discloses a tubular introducer sheath (figure 14B, element 8), a prosthesis (figure 14B, element 7), a self-expanding spring assembly (see figure 2), tubular carrier means (see figure 3, element 2); and means for retaining said prosthesis assembly at the particular position (see figure 11, element 23 and element 2). However, Inoue fails to specifically disclose barbs. Choudhury teaches using barbs to facilitate holding the graft in the blood vessel. (See figure 4, element 28.) It would have been obvious of to one of ordinary skill in the art to have incorporated barbs, as taught by Choudhury, into the design of Inoue in order to better hold the graft in the blood vessel.

Claim 30 is rejected under 35 U.S.C. § 103 as being unpatentable over Choudhury in view of Kreamer.

With respect this claim, Choudhury discloses means for retaining said prosthesis in the lumen and means for releasing said prosthesis. (See figure 4, elements 28 and 44). However, Choudhury fails to specifically disclose a sheath. Kreamer teaches using a removable sheath for introducing the graft in order to protect the blood vessel from the graft. (See column 6,

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lines 45-54.) It would have been obvious to one of ordinary skill in the art to have replaced the ties of Choudhury with the removable sheath of Kreamer in order to protect the blood vessel from the graft.

Applicant's arguments with respect to the claims have been considered but are deemed to be moot in view of the new grounds of rejection.

<sup>048</sup>  
030-14 Claims 1, 2, 5, 9-11, 16-17 and 20 are allowable over the prior art of record.

Claims 36 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication should be directed to Debra S. Brittingham at telephone number (703) 308-3401.



DEBRA S. BRITTINGHAM  
PATENT EXAMINER  
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